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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,740	04/13/2001	Daniel J. Drucker	016777-0463	2882

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/833,740	Drucker et al.
Examiner	**Art Unit**
Scott D. Priebe, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 17, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above, claim(s) *6-8* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-5 and 9-11* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Para. 0098, as amended, refers to a shaded box in Fig. 7C, which has no shaded box. Appropriate correction is required.

The amendment filed 3/17/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: para. 0020 has been amended to indicate that the southern blot shown in Fig. 4 was used to derive the schematic map shown in Figure 3. Fig. 4 clearly could not have been used to predict the schematic of Fig. 3, which was most likely derived from sequence data. As indicated in para. 0079, the blot in Fig. 4 was used to derive a map, but not the one depicted in Fig. 3. The restriction sites indicated in Fig. 3 do not match those referred to in Fig. 4. Also, Applicant has failed to indicate where the originally filed specification supports this amendment, as is required. MPEP 714.02 (3rd para. from end, last sentence) and MPEP 2163.06(l) (last sentence).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 9 is objected to because of the following informalities. The claim fails to recite the appropriate SEQ ID NO for the recited nucleotide sequence, as required by 37 CFR 1.821(d). Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-5 remain and claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 11/15/02, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Claims 1-5 remain and claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, for the reasons of record set forth in the Office action of 11/15/02, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to limit the promoter region to one which comprises "at least the last 1,000 nucleotides" of SEQ ID NO: 1 or a mammalian homolog of this sequence. However, as explained in the previous Office action, it is unclear whether even SEQ ID NO: 1 meets the limitation of "promoter region of a GLP-2 receptor gene" as it is defined in the specification. Consequently, the amendment does not address or overcome the basis for the rejection. Claim 10 recites that the promoter comprises 10.6 kb of the murine GLP-2 receptor promoter." However, the specification does not describe or disclose 10.6 kb of murine promoter in sufficient detail for one of skill in the art to distinguish it from any other 10.6 kb of DNA from another natural source, e.g. sequence of some other murine genomic location, or from an artificial

sequence, e.g. SEQ ID NO: 1 linked to heterologous sequences. Nor does the specification define promoter, only promoter region (see para. 0043)

Furthermore, the amendment is new matter. Applicant has failed to indicate where the original specification supports the limitation "at least the last 1,000 nucleotides of" or "mammalian homolog" in claim 1. The definition of a "promoter region of a GLP-2 receptor gene" in para. 0043 refers to the promoter as "comprising at least 1000 bases upstream of the transcription start site." The last 1000 nucleotides of SEQ ID NO: 1 includes 200 nucleotides downstream of the start site. The specification does not provide 1000 nucleotides of sequence for any mammalian homolog, and "at least the last 1,000 nucleotides of ... a mammalian homolog" is clearly not disclosed in sufficient detail for one of skill in the art to distinguish it from any other 1 kb of DNA from another natural source or from an artificial sequence. Applicant asserts that new claims 9-11 are supported by para. 11, 12, 14, and 69. However, these paragraphs fail to provide any support for the limitations recited in claims 9-11.

Applicant's arguments filed 3/17/03 have been fully considered but they are not persuasive. Fig. 7b shows no rat sequence upstream of the transcription start site and only 203 nucleotides of human sequence upstream of the start site. Clearly Fig. 7b does not demonstrate possession of at least 1.5 kb upstream of the start sites in rat and human. Also, as is clear from the specification, the promoter region comprises "at least 1.5 kb upstream of the start site," and more. The specification clearly fails to demonstrate that the complete promoter region, as it is defined in para. 43, has been isolated from any source including mouse, as shown by the

differences in expression patterns observed in the transgenic mouse comparing the transgene to the endogenous expression of the GLP-2R. Also, the sequence conservation was observed between mouse and human only for the first 210 nucleotides upstream of the start site, not 1.5 kb. The claims are directed to naturally occurring sequences, and as indicated in the grounds of rejection, the instant specification fails to provide those sequences as required for nucleic acid with a specified function. *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997).

Allowable Subject Matter

Claims 1-5 would be allowable if claim 1 were amended to remove reference to the "promoter region of a GLP-2 receptor region" and limit the promoter in the construct to that part of SEQ ID NO: 1 shown in the specification to be necessary and sufficient for promoter function.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

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Art Unit 1632